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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,060	12/16/2005	Leifeng Cheng	133087.09401(101081-1PUS)	1913

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EXAMINER	
TUCKER, ZACHARY C	
ART UNIT	PAPER NUMBER
1624	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/561,060	CHENG ET AL.	
	Examiner	Art Unit	
	Zachary C. Tucker	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3.* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,17,19 and 20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,17,19 and 20* is/are rejected.

7)☒ Claim(s) *2 and 4-15* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *16Dec05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Art Unit: 1624

Obviousness-Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3, 17, 19 and 20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5-7, 9, 10, 12 and 19 of copending Application No. 10/499,054. Although the conflicting claims are not identical, they are not patentably distinct from each other because the species named in claim 10 of the copending application, which are embraced by claim 1 thereof, are embraced by the indicated claims in the instant application.

Where R^1 and R^2 of the copending claims are joined to the nitrogen atom to which they are attached so as to form a 1-piperidinyl, the claims overlap with the instant claims, wherein R^3 represents a group of the formula CONH-R^z, in which R^z is a piperidinyl ring.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 3 and 17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 and 18 of

copending Application No. 10/543,264. Although the conflicting claims are not identical, they are not patentably distinct from each other because the species name in claim 18 of the copending application, which are embraced by claim 1 thereof, are embraced by the indicated claims of the instant application.

Where R^1 and R^2 of the copending claims are joined to the nitrogen atom to which they are attached so as to form a 1-piperidinyl, the claims overlap with the instant claims, wherein R^3 represents a group of the formula CONH-R^z, in which R^z is a piperidinyl ring.

There is ordinarily no patentable distinction between compositions of matter and methods. Hence, in the absence of a Terminal Disclaimer, an obviousness-type Double Patenting rejection may be made. See *In re Boylan,* 157 USPQ 370 [The patent had a composition of matter and a method of making it; the application had the method of use]; Ex parte MacAdams, 206 USPQ 445 [The patent had a composition of matter; the application had the method of use]; *Geneva Pharmaceuticals Inc. v. GlaxoSmithKline PLC*, 68 USPQ2d 1865 (CA FC 2003) [The earlier patent was drawn to method of use, the later three patents, held invalid in "Geneva II" were drawn to somewhat narrower versions of the composition of matter]; *Mosler Safe & Lock Co. v. Mosler, Bahmann & Co.*, 127 U.S. 354, 21 8 S.Ct. 1148 (1888) [the first patent was of an article; the second patent, held invalid, was for a method of making it].

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claim 19 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of obesity, bulimia, and extended abuse, addiction and/or relapse disorders, does not reasonably provide enablement for the other indications recited in the claim. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

When making the determination of scope of enablement of a claim, the Office customarily relies on the factors promulgated in the decision rendered for *In re Wands,* 858 F.2d 731,737 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), which are:

(A) The breadth of the claims;
(B) The nature of the invention;
(C) The state of the prior art;
(D) The level of one of ordinary skill;
(E) The level of predictability in the art;
(F) The amount of direction provided by the inventor;
(G) The existence of working examples; and
(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Each of these factors will be addressed, with respect to the method claimed in instant claim 19.

(A) The claim is quite broad; treatment of a wide variety of disorders is specified. Treatment of neurological disorders (in general) is specified. Treatment of memory, psychiatric, cognitive, immune, cardiovascular, reproductive and endocrine disorders (in general) is specified as well. Treating epilepsy and "related conditions" is specified also. Treatment of "diseases related to the respiratory and gastrointestinal system" is specified furthermore. Treatment of several specific diseases is also specified in the claim (schizophrenia, bipolar disorders, anxiety, anxio-depressive disorders, depression, anorexia, Parkinson's disease, Huntington's chorea, Alzheimer's disease).

(B) The nature of the invention is that of a medical treatment method.

(C) The state of the prior art is well-exemplified by the following article, authored by Di Marzo:

> Vincenzo Di Marzo et al, "Leptin-regulated endocannabinoids are involved in maintaining food intake" Nature, vol. 410, pages 822-825 (12 April 2001).

The Di Marzo article teaches that at about the time the present invention was made, in 2001, cannabinoid CB1 receptor *antagonists* were known to be plausible as treatment for overeating and/or obesity. Compounds of the present invention are antagonists or inverse agonists at the CB1 receptor. Other utilities for antagonists of the CB1 receptor were hypothesized at the time the invention was made, but the only substantial utility for which evidence had been shown was reduction food intake. As evidence that reduction of food intake/treatment of obesity/treatment of overeating was a plausible utility for CB1 receptor antagonists at the time the invention was made, the examiner would cite:

Agonists of CB1 receptor, on the other hand, were known to increase memory, decrease pain, and increase appetite among other things, at the time the invention was made. It appears that instant claim 19 embraces treatment of many disorders/diseases which are treatable with cannabinoid *agonists*, but not antagonists.

(D) The level of ordinary skill in the relevant art is that of a physician experienced in treating the recited diseases in the claim.

(E) Medical treatment methods are by no means predictable, although it can be predicted in the instant case that the full scope of instant claim 19 is not practicable with the compound according to instant claim 1, or a formulation according to instant claim 17 (see above, point "(C)").

(F) The instant specification provides guidance relating to well-understood pharmaceutical dosage forms, and alleges that the compounds of the invention are useful in the manner prescribed by instant claim 19 (pages 11-17).

(G) There are no working examples of the treatment of any condition recited in instant claim 19, by administering an effective amount of a compound of claim 1 or a formulation according to claim 17.

(H) In light of the above findings, it is presumed that in order to practice the full scope of instant claim 19, there would have to be an undue amount of experimentation conducted by whosoever would do so.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term 'epilepsy and related conditions" is not seen as being clear and well-defined, within the meaning of 35 U.S.C. 112.

Claim Objections

Claim 19, in addition to being rejected under 35 U.S.C. 112, first and second paragraphs, for reasons explained in the preceding, is objected to also because the term "neurological disorders" is repeated twice within the body of the claim.

Claims 2 and 4-15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The closest prior art with respect to instant claims 2 and 4-15 is Ohta et al, "Anti-Platelet Aggregation Activity of Some Pyrazines" Biol. Pharm. Bull., vol. 20(10), pages 1076-1081 (1997). On page 1077, several methylbenzyl-2,3-diphenylpyrazines are described, but these compounds are not embraced by instant claim 1, because when R^3

represents a group of formula $-(CH_2)_qR^9$, q must be at least 2, not 1 as is the case with the Ohta et al compounds.

Specification

The abstract of the disclosure is objected to because there is no generic structure diagram for the compounds of the invention appearing in it.

Correction is required. See MPEP § 608.01(b).

Conclusion

Any inquiry concerning this communication should be directed to Zachary Tucker whose telephone number is (571) 272-0677. The examiner can normally be reached Monday to Friday from 9:00am to 5:00pm. If Attempts to reach the examiner are unsuccessful, contact the examiner's supervisor, James O. Wilson, at (571) 272-0661.

The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

/Zachary C. Tucker/
Primary Examiner
Art Unit 1624